DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 4 2000

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The Honorable Brian Bilbray
House of Representatives
Washington, D.C. 20515

Dear Mr. Bilbray:

Thank you for your letter of October 6, 2000, co-signed by Representative Rick A. Lazio. You requested that the Food and Drug Administration (FDA or the Agency) complete action on a proposed microbiological quality standard for coliform bacteria in bottled water that was announced in the Federal Register (FR) of October 6, 1993 (58 FR 52042, the 1993 proposal). A similar response has been sent to Representative Lazio.

By way of background, it is important to note that the existing requirements of the Federal Food, Drug, and Cosmetic (FD&C) Act and regulations issued under that Act for bottled water address the safety of bottled water and are sufficiently protective of public health. FDA issued the 1993 proposal for purposes of consistency with the Environmental Protection Agency's (EPA) regulation for total coliform bacteria in public drinking water.

As you know, the 1993 proposal would change the existing FDA quality regulations for bottled water. In 1989, EPA published a final rule amending its National Primary Drinking Water Regulation for total coliform bacteria in public drinking water. At that time, section 410 of the FD&C Act required that within 180 days after EPA's promulgation of a national primary drinking water regulation, FDA was to consult with EPA and either promulgate amendments to FDA's regulations to bottled water or publish in the Federal Register reasons for not making such amendments. Although FDA determined the current regulations were protective of the public health, FDA proposed, in 1993, to change its microbiological quality standard for coliform bacteria in bottled water in order to make it consistent with EPA's 1989 final rule.

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In its 1989 rule, EPA set a maximum contaminant level goal of zero for coliform bacteria but made limited allowance for coliform bacteria to be present in public drinking water because coliforms are a persistent presence in some public water distribution systems. FDA tentatively concluded in the 1993 proposal that an allowance for the presence of coliforms in bottled water would not be appropriate since water bottlers do not use public water distribution systems to deliver finished bottled water products. Therefore, FDA proposed to revise its microbiological quality standard to provide that coliform bacteria not be present in bottled water. A number of comments were submitted to the 1993 proposal.

After carefully evaluating these comments, FDA has determined that concerns raised in the comments may not be satisfactorily addressed in a final rule. Therefore, we are considering whether to develop a new proposal to revise the microbiological quality standard for coliform bacteria in bottled water in conjunction with a withdrawal of the 1993 proposal.

Thanks again for contacting us concerning this matter. We have forwarded your correspondence to the Docket for the 1993 proposal (Docket No. 93N-0200) for inclusion in the record. If you have further questions, please let us know.

Sincerely,

Melinda Plaisier
Associate Commissioner
for Legislation

cc: Dockets Management Branch(HFA-305)

Congress of the United States
Washington, DC 20515

October 6, 2000

Dr. Jane Henney, Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Henney:

We are writing to request that the FDA finalize the standard of quality for coliform content in bottled water, as first proposed nearly seven years ago. This action would bring the federal government's standard into consistency with the bottled water industry's existing stringent standard for coliform, and would also complement the FDA's ongoing food safety initiatives.

As you are aware, the level of total coliform in bacteria in water is used to measure the microbiological quality of drinking water. Coliform is present in water contaminated with human or animal feces, and is associated with the outbreak of disease. Thus, the industry's quality standard for coliform requires that bottled water be free of coliform bacteria.

As a result, retesting for the presence of coliform bacteria should be required. This would prevent the potential for erroneous recall of products, and create consistency with the repeat monitoring scheme currently being employed by the Environmental Protection Agency (EPA) for public water systems. The FDA would be prudent to adopt the retesting scheme used in EPA's model, and should consider allowing bottlers to use the EPA approved testing methodology.

Given that the FDA has already established the need for this regulation via the 1993 proposed rule, the agency has only to make a relatively slight yet significant change to the proposed rule, and finalize the standard of quality in the interest of protecting the public health.

Thank you in advance for your consideration of our request.

Sincerely,

Member of Congress

Member of Congress

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